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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,994	01/30/2004	Mark A. Christopherson	P-11136.00 US	4525

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EXAMINER	
ADAMS, AMANDA S	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,994	CHRISTOPHERSON, MARK A.	
	Examiner	Art Unit	
	Amanda Adams	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-51* is/are rejected.

7)☐ Claim(s) *18 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group I drawn to a system, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 28, 2006.

Claim Objections

1. Claim 51 is objected to because of the following informalities: in lines 4 of the claim, "means is further for delivering" does not make sense grammatically. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 17-27, 31-35, 37, 42-45, and 47-51** are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson (US 6,353,751).

4. Swanson et al disclose the invention substantially as claimed including:

5. **Regarding claims 17 and 43**, a catheter capable of transurethral insertion (fig. 2 [18]); an ablation needle extendable from the catheter to penetrate a prostate of a

patient (col. 6 lines 25-30); an ablation energy generator to deliver ablation energy to the prostate via the ablation needle (col. 6, line 59); and a needle position indicator to present an advisory when the needle is not fully retracted within the catheter (col. 7, lines 13-20, [50]).

6. **Regarding claims 18-21, 25 and 49**, a needle position sensor to sense the position of the ablation needle (col. 7, lines 2-7, [48]), wherein the needle position sensor senses the extent to which the ablation needle is retracted or deployed from the catheter (col. 7, lines 2-12), wherein the needle position sensor includes one of a mechanical sensor, an electrical sensor, a magnetic sensor, an optical sensor, a resistive sensor, and a capacitive sensor (col. 7, lines 2-18), and wherein the needle position sensor is a continuous position sensor (col. 7, lines 15-18).

7. **Regarding claims 22-24 and 44**, Swanson et al disclose that the needle position indicator confirms when the ablation needle is fully retracted within the catheter, that the needle position indicator presents whether the ablation needle is fully deployed from the catheter, and that the needle position indicator presents the extent to which the ablation needle is deployed from the catheter (col. 7, lines 1-20, this system is capable of this limitation).

8. **Regarding claim 26**, the ablation needle includes an electrically conductive needle and wherein the needle position sensor generates a needle retracted signal when the electrically conductive needle and the needle position sensor come into electrical contact (col. 7, lines 25-30).

9. **Regarding claim 27**, the needle position sensor comprises a conductive contact ([36]; by definition, an electrode is a conductive contact).

10. **Regarding claims 31 and 47**, the position indicator comprises an audible tone (col. 16, line 34).

11. **Regarding claim 32**, the audible tone comprises an advisory activated when the needle is to be repositioned within the prostrate if the position of the ablation needle is not fully retracted within the catheter (col. 16, lines 30-37 and col. 7, lines 1-20).

12. **Regarding claim 33**, a controller to determine a time to reposition the ablation needle within the prostrate (col. 16, lines 20-37).

13. **Regarding claim 34,** the controller is connected to receive a needle position signal from the needle position sensor, and wherein the controller activates the advisory at the determined time if the needle position signal does not correspond to a needle that is fully retracted within the catheter (col. 16, lines 20-37).

14. **Regarding claim 35**, the controller generates the advisory until the needle position signal corresponds to a needle that is fully retracted within the catheter (col. 16, lines 20-37).

15. **Regarding claims 37, 45 and 48**, the position indicator comprises at least one of lights, colored lights, flashing lights, audible tones, alarms, graphical images and text messages (col. 16, line 34).

16. **Regarding claim 42**, a position sensor to continuously sense the position of the needle within the catheter, and wherein the position indicator continuously presents the sensed position of the needle (col. 7, lines 2-18).

17. **Regarding claim 51**, Swanson et al disclose means for repositioning the ablation means within the prostrate such that the ablation means is aligned with a second target tissue site within the prostrate; and wherein the ablation means is further for delivering the ablation energy to the second target tissue site (col. 6, lines 35-40; and see citation regarding claim 17).

18. **Regarding claim 50**, Swanson et al disclose a computer-readable medium containing instructions for causing a processor to: control delivery of ablation energy to a target tissue site within a prostate of a patient via an ablation needle extended from a transurethral catheter deployed within the target tissue site; receive an ablation needle position signal indicative of a position of the ablation needle within the catheter; activate an advisory if the ablation needle position signal indicates that the position of the ablation needle is not fully retracted within the catheter after delivery of the ablation energy; and continuously activate the advisory until the ablation needle position signal indicates that the position of the ablation needle is fully retracted within the catheter ([134] and see citations for cl. 17).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. **Claims 28-30 and 38-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US 6,353,751).

21. **Regarding claims 28 and 29**, Swanson et al fail to disclose a needle position sensor that indirectly senses the position of the ablation needle, wherein the position of the actuator corresponds to the position of the ablation needle, and wherein the needle position sensor senses the position of the actuator. However, due to lack of criticality in the specification, the indirect needle position sensor that detects the position of the actuator was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a direct needle position sensor that directly senses the position of the needle. Therefore, it would have been obvious to make needle-positioning sensor located on the actuator because it is capable of working equally as well as a direct positioning sensor.

22. **Regarding claim 30**, Swanson et al disclose the invention substantially as claimed above but fail to disclose a variable resistive element as the needle position sensor. However, due to lack of criticality in the specification, the variable resistive element was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conductive contact. Therefore, it would

have been obvious to use a variable resistive element because it is capable of working equally as well as a conductive contact.

23. **Regarding claims 38 and 39**, Swanson et al disclose the invention substantially as claimed but fail to disclose the position indicator located on a handle through which a user controls the position of the ablation needle and the application of ablation energy, or the position indicator located on the ablation energy generator. However, due to lack of criticality in the specification, placing the position indicator in the handle or on the ablation energy generator was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a position indicator in any other visible location. Therefore, it would have been obvious to place the position indicator on either the handle or the ablation energy generator because there it would be capable of working equally as well as placing a position indicator on any other visible location, such as a display monitor.

24. Regarding **claims 40 and 41**. Swenson et al disclose the invention substantially as claimed above but fail to disclose that the position indicator includes at least one of a graphical image and a text message presented on a user interface indicating the extent to which the ablation needle is deployed or retracted. However, due to lack of criticality in the specification, having a position indicator that is a graphical image or a text message was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to an audible position indicator. Therefore, it would have been obvious to have a graphical or textual position indicator because those are capable of alerting a surgeon equally as well as an audible position indicator.

25. Claims 36 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US 6,353,751) in view of Lundquist et al (US 5,549,644).

26. Swanson et al disclose the invention substantially as claimed above but fail to disclose the following, which is taught by Lundquist et al.

27. **Regarding claim 36**, Lundquist et al teach that a determined time to reposition an ablation needle within a prostrate is after delivery of the ablation energy (col. 26, lines 38-46). This allows ablation energy to be delivered to one specific area, and then for the device to be moved without causing harm to healthy tissue, and then for it to ablate another area of tissue. Therefore it would have been obvious to wait to reposition the device until after the ablation energy have been delivered at the first location.

28. **Regarding claim 46**, Lundquist et al teach that the means for confirming when the ablation needle is fully retracted comprises means for deactivating the advisory (col. 26, lines 38-46). This allows the advisory to be turned off once the surgeon realizes that the device has been fully retracted, so that the surgeon will be able to notice any additional changes in position; i.e. if the advisory was continuous the surgeon may incorrectly think that the ablative needle is fully retracted. Therefore it would have been obvious to include a means for deactivating the advisory.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,957,922; US 6,575,969; US 5,429,636; US 2004/0147920; and US 2002/0019627.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 10/30/06

GLENN K. DAWSON
PRIMARY EXAMINER